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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,672	06/14/2005	Peter Gerardus Cox	I-2002.024 US	4775

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Intervet/Schering-Plough Animal Health
Patent Dept. K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
08/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/539,672	COX ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10 and 11* is/are pending in the application.

4a) Of the above claim(s) *8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continuation Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/27/09 has been entered.

Response to Arguments

This Office Action is in response to the amendment submitted on 05/27/09. Claims 1-8 and 10-11 are currently pending in the application, with claim 8 having being withdrawn and claim 9 having being cancelled. Accordingly, claims 1-7 and 10-11 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's argument with respect to the rejection of claims 1-3 and 7 under 35 U.S.C. § 103(a) over Farnsworth in view of Lohuis has been fully considered. Applicant argues that the composition as presently claimed is unobvious over the prior art cited by the Examiner in view of the unexpected results. Such arguments are not persuasive as applicant is arguing features not previously present in the claims. It is noted that the

features upon which applicant relies (i.e., said pharmaceutical composition providing increased anti-inflammatory efficacy while not increasing immunosuppressive side effects and wherein the increased anti-inflammatory efficacy while not increasing immunosuppressive effects may be determined by displaying a similar leukocyte count upon administration to the non-human mammal when administered intramammarily to the non-human mammal to whom the pharmaceutical composition has not been thus administered) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Consequently, such arguments are moot. Importantly, the Examiner respectfully points out that the showing of unexpected results does not commensurate in scope with the claims. While applicant demonstrated that the combination of 300 mg of cephapirin and 20 mg of prednisolone resulted in the lowering of total PMN leukocyte counts, the claims are directed to any anti-bacterial agent at any dosage in combination with at least 20 mg of prednisolone. Applicant failed to demonstrate that all antibacterial agents in combination with 20 mg of prednisolone or higher would necessarily result in lower PMN leukocytes counts. Likewise, applicant failed to demonstrate any comparative data to show that the prior art's teaching of 250 mg and 10 mg would not necessarily result in a lowering of PMN total leukocyte counts. Finally, while applicant claims a dosage of prednisolone of at least 20 mg (i.e. 20 mg or higher), all unexpected results provided by applicant demonstrate the sole use of 20 mg of prednisolone. As a result, the Examiner contends that the unexpected results claimed by applicant do not

show that the objective evidence of nonobviousness is commensurate in scope in the claims. As a result, the Examiner maintains that Farnsworth in view of Lohuis does indeed render obvious applicant's invention.

Applicant's contention that the non-obviousness of applicant's claimed composition is illustrated in the unexpected results of the 20 mg prednisolone with the anti-bacterial compound has been fully considered. Applicant further argues that the claimed composition provided significant chemotaxis of PMN and increases the ability of the PMNs to migrate into the udder. Such arguments are not persuasive as the Examiner again reiterates the fact that applicant's show of unexpected benefits does not commensurate in scope with the present claims. While applicant illustrated an effect on chemotaxis of PMN, such effect was solely demonstrated using 20 mg of prednisolone and yet applicant's claims recite the use of 20 mg of prednisolone and any other dosage amount above 20 mg. As previously mentioned, the Examiner maintains that the unexpected show of results do not commensurate in scope with the claims. As for applicant's arguments that Lohuis teaches contrasting results wherein a substantial increase in leukocyte counts of prednisolone treated animals were observed as compared to non-treated animals, such arguments are not persuasive as the claims were not rejected over Lohuis alone but rather over the combination of Farnsworth and Lohuis. The Examiner reiterates the fact that the claims were rendered obvious over the combination of Farnsworth and Lohuis and that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of

references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As for applicant's arguments that the combined references do not teach or suggest that a person of ordinary skill in the art would have expected the same results observed by applicant, such arguments are not found persuasive as the modified reference of Farnsworth in view of Lohuis would have indeed been expected to result in similar unexpected benefits since the combined references teach the combination of an antibacterial agent along with 10 mg of prednisolone and Lohuis further teach the use of 40 mg of prednisolone in diminishing the signs of inflammation. As a result the Examiner contends that one of ordinary skilled in the art would have indeed found it obvious to expect comparable results to applicant since the instantly claimed composition and the modified composition of Farnsworth entail the same ingredients in overlapping dosages. As for applicant's arguments that Farnsworth teaches its composition for treating yeast infection-induced mastitis while Lohuis discusses the use of 40 mg of prednisolone on E. coli-induced mastitis, such arguments are not persuasive as intended use is not given patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robbie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Since both Farnsworth and Lohuis were concerned with the treatment of

mastitis, the Examiner thus contends that one of ordinary skill in the art would have indeed modified the reference in view of the teachings of the prior art references.

As for applicant's arguments that Lohuis does not teach or suggest that higher dosages of prednisolone with an antibacterial compound can provide increased anti-inflammatory efficacy while not increasing immunosuppressive side effects, such arguments are moot as they are directed to the newly amended claims which have yet to be examined. Again, the Examiner reiterates the fact that one cannot show nonobviousness by attacking references individually where the rejections are based on a combination of references. As a result, such arguments are moot. As for applicant's arguments that using higher prednisolone dosages with an anti-bacterial compound does not have similar effects as the administration of prednisolone as taught by Lohuis, such arguments are again moot as applicant's is arguing an individual reference wherein the rejection was based on a combination of references. The Examiner points out that the comparison being cited by applicant is not to the closest prior art of record. Applicants must show the criticality of varying the dosage of prednisolone while maintaining the dosage of antibacterial agent constant and vice versa in order to show true side by side comparison. As a result, the Examiner maintains that Farnsworth in view of Lohuis did indeed render obvious applicant's invention and such rejection was indeed proper.

Applicant's argument with respect to the rejection of claims 4-6 under 35 U.S.C. § 103 (a) in further view of Hornish has been fully considered. The Examiner respectfully points out that Hornish was provided to demonstrate that the use of

cephalosporins including cephapirin and cefquinome are known in the art as potent antibiotics against a broader range of organisms and in view of the fact that their use leads to enhanced transportability across the blood-membrane barrier. Thus, one of ordinary skill in the art would have found it obvious to substitute the cephalosporin antibiotics taught by Hornish for the antibiotic of Farnsworth if the desire is to treat a broader range of organisms. As a result, the Examiner maintains that Farnsworth in view of Lohuis and in further view of Hornish does indeed render obvious the aforementioned claims and such rejection was indeed proper

For the foregoing reasons, the rejections of record were indeed proper. However, in view of applicant's amendment, the following modified 103 (a) Non-Final rejections are being made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 7, and 10 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Farnsworth et al. (Canadian J. of Comp. Med. July 1975, Vol.

39, Iss. 3, pp. 340-348, previously cited) in view of Lohuis et al. (J. Dairy Sci., 1989, Vol. 72, pp. 75-98, previously cited).

It is respectfully pointed out that the recitation "said pharmaceutical composition providing increased anti-inflammatory efficacy while not increasing immunosuppressive side effects and wherein the increased anti-inflammatory efficacy while not increasing immunosuppressive effects may be determined by displaying a similar leukocyte count upon administration to the non-human mammal when administered intramammarily to the non-human mammal to whom the pharmaceutical composition has not been thus administered" has not been given patentable weight because the recitation occurs in the preamble and is an intended use in a composition. Intended use in a composition is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robbie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Farnsworth et al. teach a composition comprising an antibiotic (i.e. antibacterial agent) and steroid treatment in cows (see abstract and Materials and Methods section, pp. 341, paragraph 1, line 1). In particular, Farnsworth et al. teach the use of sterile water (i.e. carrier) as the diluent for 250 mg dihydrostreptomycin (i.e. antibacterial agent; instant claim 7) and 10 mg of prednisolone (see Materials and Methods section,

pp. 342, paragraph 6, lines 1-8) injected into the teat cistern (i.e. mammary glands) of cows (Materials and Methods section, pp. 342, paragraph 6, lines 14-15).

Farnsworth et al. do not specifically teach a composition comprising at least 20 mg of prednisolone per unit dose.

However, Lohuis et al. teach the effects of 40 mg of prednisolone on local and systemic in E. coli-induced mastitis in lactating cows (see abstract and animal section of Materials and Methods, pp. 241). In particular, Lohuis et al. teach that E. coli injection produced inflammation in the infused quarters (see pg. 241, abstract, left col., paragraph 2). Importantly, Lohuis et al. teach that corticosteroid treatments including 40 mg prednisolone led to diminished local signs of inflammation (see left col., pg. 241, abstract, last paragraph).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to discover the optimum or workable ranges of prednisolone through routine experimentation to arrive at a therapeutically effective composition since Farnsworth et al. teach a composition of prednisolone and antibiotics in an aqueous solution for effects on symptoms of mastitis and Lohuis et al. teach diminished local symptoms of mastitis after the use 40 mg of prednisolone. Moreover, one of ordinary skill in the art would have found it obvious to try 40 mg prednisolone in the combinatorial treatment of Farnsworth since Lohuis demonstrated that the use of 40 mg prednisolone

had an effect on inflammation. Thus, given the teachings of Farnsworth and Lohuis, one of ordinary skill would have been motivated to modify the composition of Farnsworth et al. with the reasonable expectation of providing a composition that is therapeutically effective and effective in deceasing inflammation.

Claims 4-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farnsworth et al. (Canadian J. of Comp. Med. July 1975, Vol. 39, Iss. 3, pp. 340-348, previously cited) in view of Lohuis et al. (J. Dairy Sci., 1989, Vol. 72, pp. 75-98, previously cited) as applicable to claims 1-3, 7, and 10 above and in further view of Hornish et al. (Current Topics in Med. Chem. July, 2002, Vol. 2, Iss. 7, pp. 717-731, previously cited).

The Farnsworth and Lohuis references are as discussed above and incorporated by reference herein. However, Farnsworth and Lohuis do not teach the use of specific cephalosporins as the antibacterial agents in the aforementioned composition.

Hornish et al. teach the use of cephalosporins for treatment of mastitis infections and/or respiratory disease in cattle (see abstract). Hornish further teaches the use of first generation cephalosporins such as cephapirin against gram positive pathogenic cocci (see table 2 and pp. 719, paragraph 1) or the use of fourth generation cephalosporins such as cefquinome with greater potency to a broader range of

organisms and enhanced transportability across the blood-membrane barrier (see table 2 and pp. 719, paragraph 4).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to substitute cephapirin or cefquinome as the anti-bacterial agent into the modified composition of Farnsworth since Hornish teaches the use of cephapirin against gram positive pathogens and the use of cefquinome for greater potency to a broad range of organisms. Thus, given the teachings of Farnsworth, Lohuis, and Hornish, one of ordinary skill would have been motivated to substitute the cephalosporins of Hornish into the modified composition of Farnsworth and Lohuis with in view of the teachings of Hornish with the reasonable expectation of providing a composition that is therapeutically effective against a broad range of organisms and composition that possesses high potency.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-5 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

07/29/2009

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617